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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

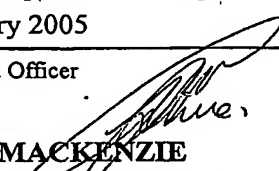
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Applicant's or agent's file reference 78270143/PS	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/AU2003/001250	International filing date (day/month/year) 23 September 2003	Priority date (day/month/year) 23 September 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61K 39/00; A61P 31/12, 31/16, 31/04, 31/22		
Applicant VITAL BIOTECH (HONG KONG) LIMITED et al		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 8 April 2004	Date of completion of the report 17 January 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  JASON MACKENZIE Telephone No. (02) 6283 7934

Box No. I **Basis of the report**

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-23 and 25-49	YES
	Claims 24	NO
Inventive step (IS)	Claims 1-23 and 27-28	YES
	Claims 24-26 and 29-42	NO
Industrial applicability (IA)	Claims 1-42	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 Cui Z, Mumper RJ. Topical immunization using nanoengineered genetic vaccines. J Control Release. 2002 May 17;81(1-2):173-84.

D2 Cui Z, Mumper RJ. Chitosan-based nanoparticles for topical genetic immunization. J Control Release. 2001 Aug 10;75(3):409-19.

Novelty (N): Claim 24

Claim 24 defines a stabilised vaccine composition comprising immunogen coated particles of a pharmaceutically acceptable water soluble material, the compositions having a moisture content between about 0.1% w/w to about 10% w/w.

D1 discloses plasmid DNA coated onto the surface of preformed chitosan-based nanoparticles, which elicit an immune response when applied topically. Claim 24 as presently drafted is considered to encompass the particles when coated with DNA (particular reference is made to the description at page 10 lines 15-20, which lists nucleic acid sequences as possible immunogens, and to appended claim 33). Therefore claim 24 is deprived of novelty.

D2 discloses plasmid DNA coated onto the surface of cationic chitosan/carboxymethylcellulose nanoparticles, and also deprives claim 24 of novelty for the same reasoning as applied to D1.

Although the methods of preparing the present invention are distinct from that of D1 and D2 (hence the novelty and inventiveness of claims 1-23), claim 24 is not limited to this preparative method.

Claims 1-23 and 25-49 appear novel in light of D1 and D2 (See further comments in Box VI).

Inventive Step (IS): Claims 24-26 and 29-42

Claim 24 is deprived of novelty as above, and consequently also lacks an inventive step. D1 and D2 are directed to the preparation of DNA vaccines using carrier nanoparticles. These documents use luciferase and galactosidase plasmids as "model antigens", coated onto chitosan beads. The experiments show that administration of these coated beads results in successful expression of the plasmid genes. The person skilled in the art is consequently being led to coat chitosan beads with viral and bacterial immunogens, that is, to prepare DNA vaccines. Claim 24 is considered to encompass said vaccine compositions within its scope. The added features of appended claims 25-26, and 29-42 are not considered to import any patentability.

Claims 1-23, 27-28, and 43-49 appear to be inventive in light of D1 and D2.

Industrial Applicability (IA): Claims 1-42

Claims 1-42 are industrially applicable.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2003/001250

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No.</u> <u>Patent No.</u>	<u>Publication date</u> <u>(day/month/year)</u>	<u>Filing date</u> <u>(day/month/year)</u>	<u>Priority date (valid claim)</u> <u>(day/month/year)</u>
P, X WO 2003/061629	31 July 2003	23 January 2003	25 January 2002

WO 2003/061629 discloses vaccine compositions containing antigens coated into biodegradable beads. If these documents had been published before the priority date of the present application claims 24, 25 and 28-42 may not be considered novel. These documents may be considered relevant in some jurisdictions.

Although the methods of preparing the present invention are distinct from that of WO 2003/061629, claim 24 and the appended claims thereto are not limited to this preparative method.

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure</u> <u>(day/month/year)</u>	<u>Date of written disclosure</u> <u>referring to non-written disclosure</u> <u>(day/month/year)</u>
_____	_____	_____